

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
 United States Patent and Trademark
 Office
 Box PCT
 Washington, D.C.20231
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 18 May 2000 (18.05.00)	
International application No. PCT/US99/21509	Applicant's or agent's file reference 6300.96a
International filing date (day/month/year) 17 September 1999 (17.09.99)	Priority date (day/month/year) 18 September 1998 (18.09.98)
Applicant FRAZIER, A., Bruno et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 04 April 2000 (04.04.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

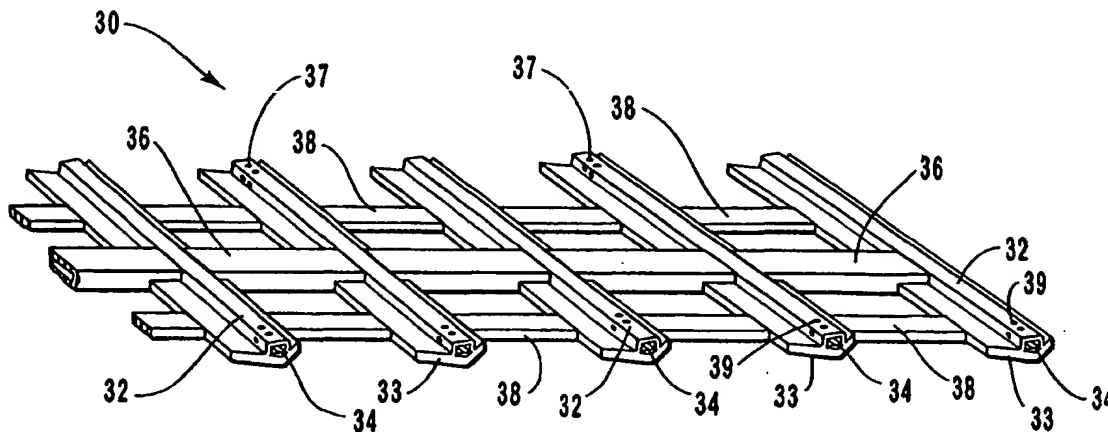
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer F. Baechler Telephone No.: (41-22) 338.83.38
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: A61M 5/32	A1	(11) International Publication Number: WO 00/16833 (43) International Publication Date: 30 March 2000 (30.03.00)
(21) International Application Number: PCT/US99/21509 (22) International Filing Date: 17 September 1999 (17.09.99) (30) Priority Data: 60/101,064 18 September 1998 (18.09.98) US (71) Applicant (for all designated States except US): THE UNIVERSITY OF UTAH RESEARCH FOUNDATION [US/US]; Suite 110, 615 Arapen Drive, Salt Lake City, UT 84108 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): FRAZIER, A., Bruno [US/US]; 609 East 7th Avenue, Salt Lake City, UT 84103 (US). BRAZZLE, John, D. [US/US]; 133 West 800 North, Clearfield, UT 84015 (US). (74) Agents: SEELEY, David, O. et al.; Workman, Nydegger & Seeley, 1000 Eagle Gate Tower, 60 East South Temple, Salt Lake City, UT 84111 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: SURFACE MICROMACHINED MICRONEEDLES



(57) Abstract

Surface micro-machined micro-needles (32) are formed as single needles (32) or in two-dimensional or three-dimensional micro-needle arrays (30). The micro-needles (32) are fabricated on a substrate (12) which can remain attached to the micro-needles (32) or can be subsequently removed. The two-dimensional or three-dimensional micro-needle arrays (30) can have cross-coupling flow channels (36) which allow for pressure equalization, and balance of fluid flow within the micro-needle arrays (30). Each of the micro-needles (32) has a micro-channel (36) therethrough that provides communication between at least one input port (37) at a proximal end of the micro-needles (32), and at least one output port (39) at an opposite distal end.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
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BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
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CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
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CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
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DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/21509

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 5/32

US CL :604/264

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/264, 272, 273, 274; 600/222, 223, 224, 181

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,591,139 A (LIN et al.) 07 January 1997, Abstract, Figs. 3A-1 to 3B-2, col. 4 line 48 to col. 5 line 10.	1-53
A	US 5,312,456 A (REED et al.) 17 May 1994, col. 3 lines 35-46, col. 5 lines 8-20, col. 6 lines 11-28, Fig. 13.	1-53

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

01 DECEMBER 1999

Date of mailing of the international search report

17 DEC 1999

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

SHARON ELIZABETH KENNEDY

Telephone No. (703) 305-0154

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: DAVID O. SEELEY
WORKMAN, NYDEGGER & SEELEY
60 EAST SOUTH TEMPLE
1000 EAGLE GATE TOWER
SALT LAKE CITY, UTAH 84111

PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

07 JUL 2000

Applicant's or agent's file reference

6300.96A

IMPORTANT NOTIFICATION

International application No.

PCT/US99/21509

International filing date (day/month/year)

17 SEPTEMBER 1999

Priority Date (day/month/year)

18 SEPTEMBER 1998

Applicant

THE UNIVERSITY OF UTAH RESEARCH FOUNDATION

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

SHARON KENNEDY

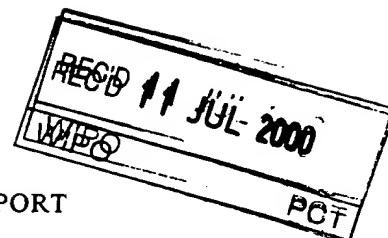
Telephone No. (703) 305-0154

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 6300.96A	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/21509	International filing date (day/month/year) 17 SEPTEMBER 1999	Priority date (day/month/year) 18 SEPTEMBER 1998
International Patent Classification (IPC) or national classification and IPC IPC(7): A61M 5/32 and US Cl.: 604/264		
Applicant THE UNIVERSITY OF UTAH RESEARCH FOUNDATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.	
2. This REPORT consists of a total of <u>3</u> sheets. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of <u>0</u> sheets.	
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step or industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application	

Date of submission of the demand 04 APRIL 2000	Date of completion of this report 04 MAY 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer SHARON KENNEDY Telephone No. (703) 305-0154

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/21509

I. Basis of the report

1. With regard to the elements of the international application: *

☒ the international application as originally filed☒ the description:

pages 1-15 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of

☒ the claims:

pages 16-20 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of

☒ the drawings:

pages 1-7 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of

☒ the sequence listing part of the description:

pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
☒ the claims, Nos. NONE
☒ the drawings, sheets/fig. NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/21509

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)

Claims	<u>1-53</u>	YES
Claims	<u>NONE</u>	NO

Inventive Step (IS)

Claims	<u>1-53</u>	YES
Claims	<u>NONE</u>	NO

Industrial Applicability (IA)

Claims	<u>1-53</u>	YES
Claims	<u>NONE</u>	NO

2. citations and explanations (Rule 70.7)

Claims 1-53 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the hollow non-silicon microneedles as claimed.

----- NEW CITATIONS -----
NONE

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: DAVID O. SEELEY
WORKMAN, NYDEGGER & SEELEY
60 EAST SOUTH TEMPLE
1000 EAGLE GATE TOWER
SALT LAKE CITY, UTAH 84111

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 6300.96A	Date of Mailing (day/month/year) 17 DEC 1999
International application No. PCT/US99/21509	International filing date (day/month/year) 17 SEPTEMBER 1999
Applicant THE UNIVERSITY OF UTAH RESEARCH FOUNDATION	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.


Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

 **DOCKETED**
 BY ON 12-22-99
 RESPONSE DUE 2-1-00

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

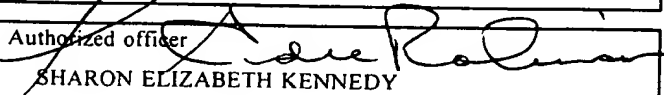
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  SHARON ELIZABETH KENNEDY
Facsimile No. (703) 305-3230	Telephone No. (703) 305-0154

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 6300.96A	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US99/21509	International filing date (day/month/year) 17 SEPTEMBER 1999	(Earliest) Priority Date (day/month/year) 18 SEPTEMBER 1998
Applicant THE UNIVERSITY OF UTAH RESEARCH FOUNDATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (See Box I).
2. ☐ Unity of invention is lacking (See Box II).
3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing

☐ filed with the international application.
☐ furnished by the applicant separately from the international application,

☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.

☐ transcribed by this Authority.
4. With regard to the title,

☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:
5. With regard to the abstract,

☐ the text is approved as submitted by the applicant.
☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:
 Figure No. 2A

☐ as suggested by the applicant.
☒ because the applicant failed to suggest a figure.
☐ because this figure better characterizes the invention.

☐ None of the figures.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The technical features mentioned in the Abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

NEW ABSTRACT

Surface micro-machined micro-needles (32) are formed as single needles (32) or in two-dimensional or three-dimensional micro-needle arrays (30). The micro-needles (32) are fabricated on a substrate (12) which can remain attached to the micro-needles (32) or can be subsequently removed. The two-dimensional or three-dimensional micro-needle arrays (30) can have cross-coupling flow channels (36) which allow for pressure equalization, and balance of fluid flow within the micro-needle arrays (30). Each of the micro-needles (32) has a micro-channel (36) therethrough that provides communication between at least one input port (37) at a proximal end of the micro-needles (32), and at least one output port (39) at an opposite distal end.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/21509

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 5/32

US CL : 604/264

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/264, 272, 273, 274; 600/222, 223, 224, 181

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,591,139 A (LIN et al.) 07 January 1997, Abstract, Figs. 3A-1 to 3B-2, col. 4 line 48 to col. 5 line 10.	1-53
A	US 5,312,456 A (REED et al.) 17 May 1994, col. 3 lines 35-46, col. 5 lines 8-20, col. 6 lines 11-28, Fig. 13.	1-53

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier document published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

01 DECEMBER 1999

Date of mailing of the international search report

17 DEC 1999

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

SHARON ELIZABETH KENNEDY

Telephone No. (703) 305-0154